



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/533,833

05/03/2005

Masahiro Kajino

Q101061

7356

23373 7590 07/31/2009
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

07/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,833	Applicant(s) KAJINO ET AL.	
	Examiner JOHN MABRY	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 (in part), 13-19, 21-23, 26 (in part), 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 11 (in part), 18, 19 and 26 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 (in part), 13-17, 21-23, 26 (in part), 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1625

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2009 has been entered.

Response to Applicant's Remarks

Applicant's response on March 24, 2009 filed in response to the Office Action dated November 24, 2008 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 11 (in part), 13-17, 21-23, 26 (in part), 28 and 29 are pending and rejected.

Claims 1-10, 12, 20, 24, 25 and 27 have been cancelled.

Claims 11 (in part), 18, 19 and 26 (in part) are directed towards non-elected subject matter.

35 USC § 112 Rejection(s)

The 112-1st rejection of claims regarding the scope of enablement for "R3" has been overcome in view of Applicants amending the claims.

Claim Rejections - 35 USC § 103

Claims 11 (in part), 13-17, 21-23, 26 (in part), 28 and 29 rejections are maintained under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 4,831,192).

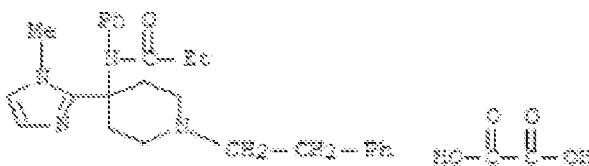
Applicant argues that Examiner failed to state a reason why one of ordinary skill in the relevant art would obtain Applicant's claimed compound from Lin et al (US '192).

Art Unit: 1625

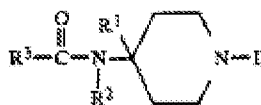
Examiner respectfully disagrees with this allegation. As previously stated in Non-Final rejection (dated 5/21/09) and maintained in Final rejection (dated 11/24/08), the following obviousness rejection was set forth over Lin et al:

Scope & Content of Prior Art MPEP 2141.01

Lin et al discloses compounds and compositions of Formula I''' wherein R2b=ethyl, R1b= 1-methyl-2-imidazol-2-yl, Z1= -CH₂CH₂- and R3=phenyl (see Compound 1, column 45/46). Pharmaceutical compositions are taught in column 3, line 61.



Examiner clearly stated that the only difference between the claimed compounds and the stated art reference was the Z1 position: Lin's -CH₂CH₂-phenyl versus Applicant's -CH₂-phenyl which are homologues AND Lin et al teaches that compound of the following formula wherein L can be an unsubstituted or substituted phenylalkyl (which Applicant claims).



L is lower alkyl, lower alkoxy, thienyl lower alkyl, thiazolyl lower alkyl which can be substituted in the 4-position with a lower alkyl; (4,5-di-hydro-5-oxo-1H-tetrazol-1-yl) lower alkyl which can be substituted in the 4-position with a lower alkyl, pyrazolyl lower alkyl, pyridinyl lower alkyl, oxo phenyl lower alkyl, N-phthalimido lower alkyl, 2-4-(1H,3H)-pyridine-dionyl, disubstituted in the 3 position with lower alkyl; and unsubstituted and substituted phenyl lower alkyl in which the substituents are selected from the group consisting of lower alkyl, lower alkoxy, halogen, lower haloalkyl (preferably trifluoroalkyl) or combinations thereof.

The elected invention is compounds of Formula (I'''). Examiner has clearly rejected Applicant's claimed compounds over the prior art. The claimed compounds are properly rejected as being obvious over Lin et al. Examiner only stated the use (treatment) of the compounds of Lin et al in order to rebut the arguments of Applicant. Examiner simply wanted to make the following point:

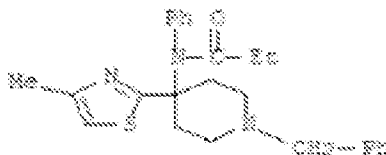
Applicant's compounds are intended to regulate neuromedin U receptor. Regulation of neuromedin U receptor which has a number of potential diverse functions including contraction of smooth muscle, regulation of blood pressure, pain perception, appetite, bone growth, and hormone release. Lin's compounds which are structurally similar are disclosed to regulate muscle coordination, respiratory depression, heart rate decrease and arterial pressure decrease (see column 1, lines 31-39). The compounds of Lin and the instant application are drawn to treat similar and overlapping diseases, disorders and conditions. Considering this evidence, one of ordinary skill in the art would be motivated to use the reference of Li in order to achieve the instantly claimed compounds and its claimed uses.

Claims 11 (in part), 13-17, 21-23, 26 (in part), 28 and 29 rejections are maintained under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 4,871,749 and US 4,791,120) in view of Kudzma et al (J. Med. Chem. 1989, 32, 2534-42).

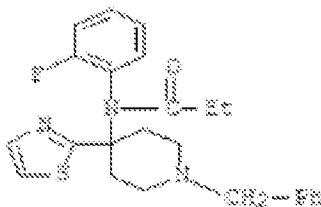
Examiner is confused. Applicant argues that "a corresponding compound of the formula (I''') wherein Z1 is ethylene..." (see second paragraph, page 7 of Applicant's arguments dated 3/24/09). First of all, Applicant claims compounds of formula (I''') wherein Z1 is methylene. Secondly, Examiner rejected the claimed compounds as being obvious over Lin and Kudzma (see below).

Scope & Content of Prior Art MPEP 2141.01

Lin et al discloses compounds and compositions of Formula I''' wherein R2b=ethyl, R1b= 4-methyl-2-thiazolyl, Z1=CH2 and R3=phenyl (see Example 3, column 10). Pharmaceutical compositions are taught in column 3, lines 42-42. The oxalate salts are taught in column 3, lines 50-51.



Kudzma et al discloses compounds and compositions of Formula I''' wherein R2b=ethyl, R1b= 4-methyl-2-thiazolyl, Z1=CH2 and R3=2-fluoro-phenyl (see compound 8e, page 2535, Scheme 1) (PTO-1449).



Applicant alleges that Z1 being methylene is widely used as a protecting groups. According to the primary references of Lin et al (US 4,871,749 and US 4,791,120), the Z1 being methylene is not used as a protecting group (see entire references). Additionally, the instant application claims compounds and Examiner has rejected the instant application using compounds. The Kudzma reference is a secondary reference and used as a supplemental reference in order to support the obviousness of structural features in Examiner's argument. Also, Applicant has failed to address Examiner's H vs CH₃ and homolog (methyl vs ethyl) arguments made in said obviousness argument.

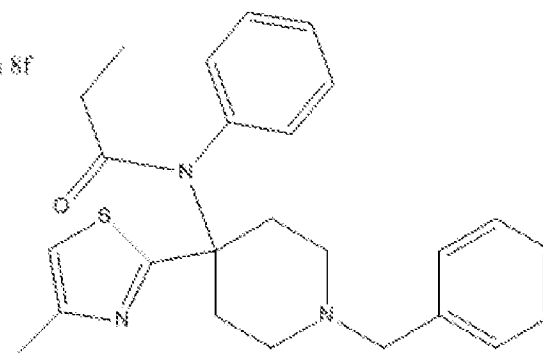
The declaration under 37 CFR 1.132 filed March 24, 2009 is insufficient to overcome the rejection of claims 11 (in part), 13-17, 21-23, 26 (in part), 28 and 29 based upon 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 4,871,749 and US 4,791,120) in view of Kudzma et al (J. Med. Chem. 1989, 32, 2534-42) as set forth in the last Office action because of the following.

The declaration compares the compounds of Kudzma's versus the compounds of the instant application. The proper comparison should be between the compounds of Lin versus the compounds of the instant claimed invention.

Examiner acknowledges the IC₅₀ human neuromedin U receptor binding results in Table on page 5 of declaration. However, this is not sufficient to overcome the obviousness rejection of record. The following compounds are disclosed in the declaration submitted 3/24/09.

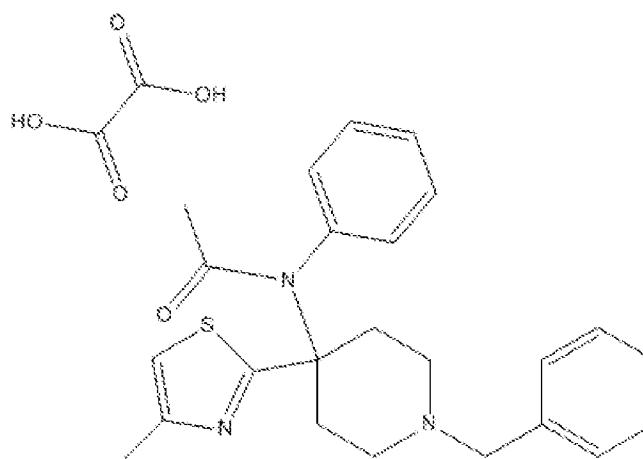
Art Unit: 1625

Compound A - Kudzma 8f



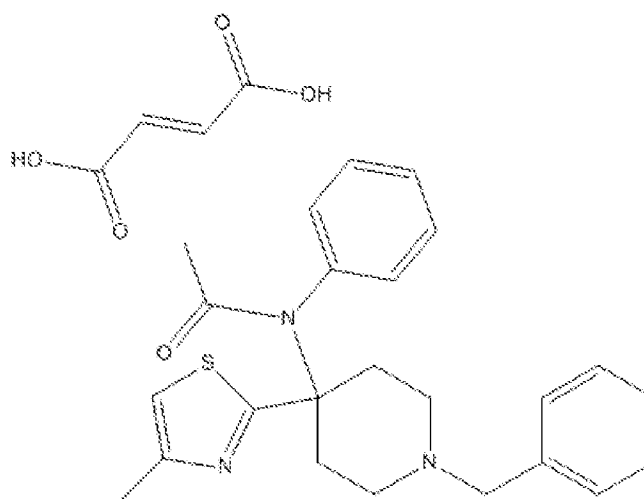
N-[1-benzyl-4-(4-methylthiazol-2-yl)-4-piperidinyl]-N-phenylpropionamide

Compound B



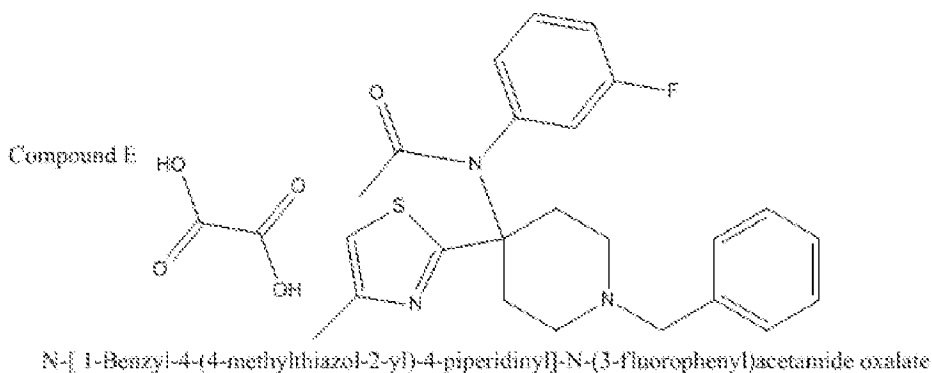
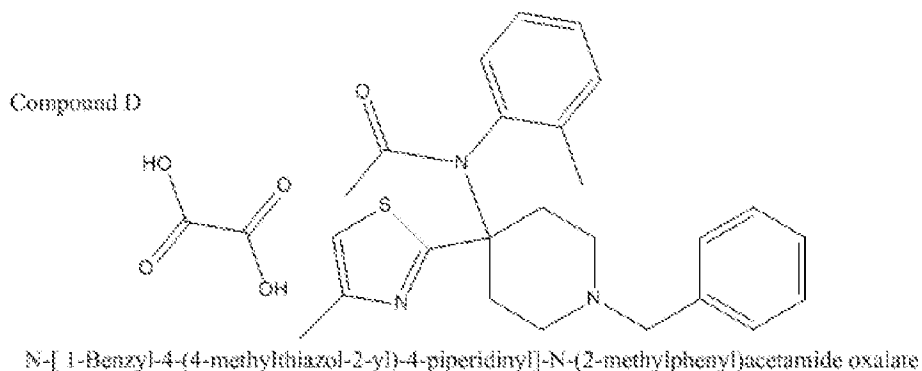
N-[1-Benzyl-4-(4-methylthiazol-2-yl)-4-piperidinyl]-N-phenylacetamide oxalate

Compound C



N-[1-Benzyl-4-(4-methylthiazol-2-yl)-4-piperidinyl]-N-phenylacetamide fumarate

Art Unit: 1625



The instant claimed invention deemed obvious in view of rejection of record, more specifically, the references of Lin et al (US 4,871,749 and US 4,791,120) for several reasons.

a) one of the differences between Applicant's species above and that of Kudzma's 8f is the corresponding R2b variable. The examples above all show a CH₃ and Kudzma's 8f has an -CH₂CH₃. Applicant claims compounds of Formula (I''') where R2b is C1-6 alkyl. The compound of Kudzma's clearly falls within this claimed range.

b) another difference between Applicant's species above and that of Kudzma's 8f is the corresponding salts (anions). The references of Lin et al disclose and teach pharmaceutically acceptable salts.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

This is a request for continuation of the same application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

Application/Control Number: 10/533,833
Art Unit: 1625

Page 12

/Rita J. Desai/

Primary Examiner, Art Unit 1625